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PATENT

Attorney Reference Number 5585-59367
Application Number 09/869,564

Remarks

Claims 1-42 were pending in the application. No claims are added or cancelled. Therefore, claims 1-42 are still pending.

Applicants thank Examiner Tung for clarifying to Applicants' representative Sheree Lynn Rybak, Ph.D. that a species election is not necessary if Group 1 is elected, during a telephone conversation on October 29, 2003.

It appears that the incorrect standard was applied to the present application, which is a U.S. National Stage application. Therefore, the PCT unity of invention standard should be applied to the pending claims. As set forth in 37 C.F.R. § 1.475, the unity of invention standard notes that unity is satisfied if there is a technical relationship among the inventions involving the same special technical features. "Special technical features" are those which define a contribution which each of the claimed inventions makes over the prior art. In the corresponding International Preliminary Examination Report (IPER), claims 1-3, 8, 10-12, 14-17, and 20 were found to be novel and inventive over the prior art. This finding should be taken into account when formulating the restriction requirement in the corresponding U.S. National Stage application, because international prosecution has already determined that the patentable claims do share special technical features that establish unity of invention. However, no mention of this finding was made in the October 1, 2003 restriction requirement, which did not explain why the special technical features would now be disregarded. Since the unity of invention standard of 37 C.F.R. § 1.475 was not applied, a *prima facie* case was not established to support the present restriction requirement. Applicants respectfully request that the PCT unity of invention standard be applied to the present application, in which case the claims that were already examined and found to be patentable should be maintained in the present case, in the absence of some citation of new prior art that overcomes the special technical features that have already been found to unify these claims. If the U.S. Patent and Trademark Office contends that the claims do not share a special technical feature that distinguishes the prior art, then the prior art which allegedly defeats this common nucleus of patentable subject matter should be cited.

In addition, reconsideration of the restriction requirement is requested, because the restriction requirement did not explain the reasons underlying the conclusion that there are thirteen different inventions. Instead, the restriction requirement on pages 4-5 merely re-states what each of the groups is directed to, but fails to provide any reasoning as to why they fail to satisfy the requirements for unity set forth above. In the absence of any articulated reasons underlying the restriction, a *prima facie* case has not been established to support the present restriction requirement.

The Applicants believe that several groups of inventions should be recombined for the following reasons. Claims 1-3, 8, 10-12, 14-17, and 20 were found in the IPER to be patentable. These claims are directed to an isolated nucleic acid that can hybridize to SEQ ID NO: 1 under high stringency conditions (Group I), a delivery vehicle including the nucleic acid or protein (Group III), antibodies (Group IV), methods of using the antibodies (Group V),and methods of treating orofacial clefting (Group VI). Therefore, the groups that include these claims, Groups I and III - VI, should be recombined under the PCT unity of invention standard.

Even using the standard in the United States under 35 U.S.C § 121, several of the claim groups should be recombined. Group I (directed to an isolated nucleic acid), Group III (directed to a delivery vehicle including the nucleic acid), Group VI (directed to a method of using the nucleic acid to treat orofacial clefting), and Group VII (directed to a pharmaceutical composition including the nucleic acid) are inherently interconnected. In order to perform a thorough search of the prior art relevant to the nucleic acid of Group I (claims 1-6, 36, and 38-40), the prior art relevant to methods of using the nucleic acid, and delivery vehicles and pharmaceutical compositions including the nucleic acid (claims 1-4, 8-9, and 14-18) will have to be searched. In addition, if the nucleic acid of Group I is found to be novel and non-obvious in view of the prior art, then methods of its use and compositions that include the nucleic acid are also novel and non-obvious. Therefore, there is no additional burden on the Examiner to search the claims in Groups I, III, VI, and VII in a single application. In the absence of any burden on the U.S. Patent and Trademark Office, Groups I, III, VI, and VII should be examined in the same application.

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Similarly, Group II (directed to an isolated protein), Group III (directed to a delivery vehicle including the protein), Group VI (directed to a method of using the protein to treat orofacial clefting), and Group VII (directed to a pharmaceutical composition including the protein) are inherently interconnected. In order to perform a thorough search of the prior art relevant to the protein of Group II (claims 7, 22 and 41-42), the prior art relevant to methods of using the protein, and delivery vehicles and pharmaceutical compositions including the protein (claims 7-9, and 14-18) will have to be searched. In addition, if the protein of Group II is found to be novel and non-obvious in view of the prior art, then methods of its use and compositions that include the protein are also novel and non-obvious. Therefore, there is no additional burden on the Examiner to search the claims in Groups II, III, VI, and VII in a single application. In the absence of any burden on the U.S. Patent and Trademark Office, Groups II, III, VI, and VII should be examined in the same application.

If the Examiner has any questions regarding this response, she is invited to telephone the undersigned.

Respectfully submitted,

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